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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/886,779 | 06/21/2001 | Chandran R. Sabanayagam | 701586/50113-C | 6933 |

50607 7590 01/26/2007

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| EXAMINER |
|---|
| LU, FRANK WEI MIN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/886,779 | SABANAYAGAM ET AL. | |
| | Examiner | Art Unit | |
| | Frank W. Lu | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11 and 23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

***CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE filed on October 30, 2006 and the amendment filed on April 3, 2006 have been entered. The claims pending in this application are claims 11 and 23-38.

### *Claim Objections*

2. Claims 11 and 23 are objected to because of the following informality: "a unique 3' terminus" in step d) should be "an unique 3' terminus".

3. Claim 30 is objected to because of the following informality: "a unique 3' terminus" in line 12 should be "an unique 3' terminus".

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claims 11 and 23-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "said extended immobilized oligonucleotide has a unique 3' terminus resulting from the termination of the amplification of the sequence of interest" is added to the newly amended independent claims 11 and 30 and the limitation "said extended immobilized oligonucleotide has a unique 3' terminus, namely, the 3' terminus that extends in the direction of z-dimension varies according to the sequence of interest" is added to the newly amended independent claim 23. Although pages 10-12 and Figures 2 and 3B-3C of the specification describe "each circular DNA template added has a unique sequence of interest (e.g., a different sequence corresponding to a unique portion of a target)" and "extended strands comprising two or more (and more typically three or more, and more preferably, ten or more, and still more preferably more than fifty) copies of the sequence of interest", pages 10-12 and Figures 2 and 3B-3C of the specification fails to define or provide any disclosure to support that said extended immobilized oligonucleotide has an unique 3' terminus resulting from the termination of the amplification of the sequence of interest as recited in claims 11 and 30 and said extended immobilized oligonucleotide has a unique 3' terminus wherein the 3' terminus extends in the direction of z-dimension varies according to the sequence of interest as recited in claim 23.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a

claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application". MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 11 and 23-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.,* (US Patent No. 5,753,439, filed on May 19, 2003).

Smith et al., teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about

10,000 different probes (see column 9, lines 18-34). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1 and 2).

Regarding claims 11 and 23, since claims 11 and 23 are directed to a product (an ordered redundant array of immobilized oligonucleotides) and are not directed to a method, the method steps recited in claims 11 and 23 which are used to make the ordered redundant array of immobilized oligonucleotides are no patentable weight and claims 11 and 23 are product-by-process claims. Note that it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.". *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Since claims 11 and 23 are directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate while Smith *et al.,* teach an array comprising 10 to 10,000 different probes with 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), Smith *et al.*, disclose an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., repeats) as recited in claims 11 and 23. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end

has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claim 30, claim 30 is directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate and each sequence of interest is different for each extended immobilized oligonucleotide. Since Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34 and column 15, claims 1 and 2), Smith *et al.*, teach an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., repeats) and each sequence of interest (ie., each of repeat sequences) is different and can bind to a different target nucleic acid. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claims 24-29 and 31-33, since these different probes taught by Smith *et al.*, have 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), claims 24-29 and 31-33 are anticipated by Smith *et al.*.

Regarding claims 34-38, different probes on the arrays in Figures 6A to 6C taught by Smith *et al.*, have 10-109 repeats wherein 5' and 3' ends of these probes are labeled with biotin

and rhodamine respectively. Target nucleic acids comprising 88, 55, and 17 repeats with a fluorescein at their 3' ends are hybridized with an identical array in separate experiments and digested with S1 nuclease. Then strand displacement assays are performed. When the probe contains more internal repeats than the target, the rhodamine label is lost in the strand displacement and the resultant product is red. Similarly, when the target contains more internal repeats than the probe, the fluorescein label is lost and the product is green. When the probe and the target both contain the same number of repeats, both rhodamine and fluorescein remain and the resultant color is yellow (see column 12, example 4, and Figures 6A to 6C). When target nucleic acids comprising 88, 55, and 17 repeats hybridize with their corresponding probes (having 88, 55, and 17 repeats) on the array, the resultant colors must be yellow. Therefore, Smith *et al.*, teach that at least two copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claims 34 and 35, at least ten copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 37, and at least fifty copies of a fragment of a template nucleic acid (ie., 88 or 55 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeat of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 38.

Therefore, Smith *et al.,* teach all limitations recited in claims 11 and 23-38.

***Response to Arguments***

In page 8, third paragraph of applicant's remarks, applicant argues that "[A]pplicants submit that the product of the present invention differs from the product of Smith in that the oligonucleotide probes in the arrays of the present invention have been extended at their 3' termini thus resulting in differing 3' termini according to the sequence of interest. The 3' terminus of each strand of the Smith array is always the same. The array of Smith comprises oligonucleotide probes that each have 100% identical 5' and 3' ends. This is not the same with the claimed arrays. They can be produced by a process such as RCA of the sequence of interest in the z-dimension. The sequence of interest differs from strand to strand in for example, claim 11. The 3' terminus in the z-dimension will differ depending on the sequence of interest. It will also vary depending upon where the amplification terminates".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since, as shown in above rejection under 35 USC 112, first paragraph, the limitation "said extended immobilized oligonucleotide has a unique 3' terminus resulting from the termination of the amplification of the sequence of interest" recited in claims 11 and 30 and the limitation "said extended immobilized oligonucleotide has a unique 3' terminus, namely, the 3' terminus that extends in the direction of z-dimension varies according to the sequence of interest" recited in claim 23 are new matters and should be removed from claims 11, 23, and 30, in view of new matters in claims 11, 23, and 30, the rejection under 35 USC 102 is maintained.

***Conclusion***

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

January 19, 2007

FRANK LU
PRIMARY EXAMINER